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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,667	01/25/2002	Scott Smith	760-12 DIV	4339

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EXAMINER

AFTERGUT, JEFF H

ART UNIT	PAPER NUMBER
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1733

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,667

Applicant(s)

SMITH, SCOTT

Examiner

Jeff H. Aftergut

Art Unit

1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 11, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5, 11, and 20, the applicant recited that the planar graft material is a “non-textile strip” of material. However, each independent claim from which these claims depend respectively recite that the planar graft is a “non-woven planar graft”. A “non-woven” is a textile material. These dependent claims are therefore in opposition to what is claimed in the independent claims. It is suggested in each instance that claims 5, 11, and 20 be revised to delete that the strip is a “non-textile” strip material. It would appear from the disclosure that the “non-textile” materials envisioned by applicant were expanded PTFE layers.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-9, 11-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (US 5,824,040) in view of either one of Shannon et al (5,928,279) or Brauker et al (6,517,571) and any one of Pinchuk (5,755,774, newly cited), Fogarty et al (5,800,520, newly cited), or Dereume et al (5,723,004 newly cited).

The references to Cox, Shannon et al and Brauker et al are discussed in full detail in the

Art Unit: 1733

Office action dated January 14, 2004, paragraphs 3 and 5. Applicant is referred to these paragraphs for a complete discussion of these references. The references failed to expressly state that the graft material would have been formed from a nonwoven material. It should be noted that the stent component in Cox was longitudinally disposed (disposed along the length of the strip material) and that it was secured to the strip material in this condition via stitching for example. The reference therefore suggested that the stent wire was attached lengthwise along the strip of graft material.

Each one of Pinchuk, Fogarty et al, or Dereume et al suggested that those skilled in the art of manufacturing a graft material would have employed nonwoven materials for the graft component of the implantable materials described therein. More specifically, the reference to Pinchuk at Figure 1, column 4, lines 27-39, column 4, lines 50-52, column 5, lines 61-column 6, line 1, column 6, lines 6-16. Note that in Pinchuk the reference is manufacturing a stent graft assembly with a stent material having the same shape as applicant's stent. Clearly, the stent having the sinusoidal shape would have been attached to the graft material in the lengthwise direction. The reference to Fogarty et al suggested that one skilled in the art at the time the invention was made would have utilized a nonwoven material for the graft of a stent and graft assembly, see column 9, line 55-column 10, line 5. Note that the stent component (the self expanding wire component) is attached to the graft material and again that those skilled in the art would have understood that the liner and/or graft component would have been a nonwoven material. The reference to Dereume et al suggested that those skilled in the art would have formed a stent graft assembly wherein the graft material employed for the layers 23 and 24 were formed from nonwoven fiber layers in the assembly. As one skilled in the art would have been

Art Unit: 1733

expected to select suitable materials for the stent employed as well as the graft assembly utilized in the assembly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the nonwoven strip materials of any one of Pinchuk, Fogarty et al, or Dereume et al in the process of making a stent graft assembly wherein a stent was disposed between two strips of the graft material in order to provide a smooth and uniform final product as suggested by either one of Shannon et al or Brauker et al in the process of making a stent graft assembly as taught by Cox et al.

5. Claims 10 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as set forth above in paragraph 4 further taken with Martin et al (6,361,637) for the same reasons as expressed in the Office action dated January 14, 2004, paragraph 6.

Response to Arguments

6. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has amended the claims to recite that the planar material is a non-woven. The meaning of a non-woven in this art is known per se. Applicant is advised that claims 5, 11, and 20 are somewhat confusing as they recite that the material for the layer is a "non-textile" and each of these claims depend from an independent claim which recited that the strip material was a non-woven. A non-woven is understood in the art to be a textile material. Claims 5, 11, and 20 are therefore confusing and it is not understood what applicant intends by these claims (although it would seem that applicant in the specification distinguished a nonwoven from an expanded polytetrafluoroethylene).

Art Unit: 1733

Regarding the prior art rejection and the reference to Cox et al, the applicant argues that Cox et al is not a 102 because the reference did not teach that the graft material of the assembly which was in the form of a planar strip was formed from a non-woven material. Applicant also argues that the stent component is not attached lengthwise along the length of the planar strip. These arguments are respectfully traversed.

First, any one of Pinchuk, Fogarty et al, or Dereume et al suggested that one skilled in the art at the time the invention was made would have known to form the graft component of the stent graft assembly from a non-woven material. Even assuming, for arguments sake, that the graft materials of Pinchuk, Fogarty et al, or Dereume et al were applied and/or assembled to the stent in another manner than that claimed, one skilled in the art would have still been motivated to utilize the conventional materials that the graft was formed from in the manufacture of the stent graft. Doing so in Cox et al would have resulted in a planar strip of nonwoven material which was initially assembled with a stent component in a planar form and then the planar strip would have been wound upon a mandrel to form the stent graft assembly. While it is additionally agreed that the references to Shannon et al or Brauker et al assembled the components together differently, this is not the basis for the prior art rejection. The rejection is that one skilled in the art at the time the invention was made would have readily appreciated the various types of materials useful for the graft and the stent components in the arrangement and would have selected suitable materials for processing according to Cox et al. Note that Cox et al does not expressly recite the make up of the graft material in the envisioned operation and one skilled in the art would have been expected to look to the stent-graft arts to find suitable materials for the

Art Unit: 1733

processing. Such clearly included nonwoven layers as such were known per se as graft materials in the art.

Regarding applicant's second argument that the reference to Cox does not teach the lengthwise attachment of the stent to the graft strip material in Cox, the applicant is advised that the stent material was stitched to the graft material (the strip) in the disclosure of Cox. As the stent and graft materials are attached and both extend in the lengthwise direction of the strip, one would have expected that the stent component was attached to the strip of graft material in the lengthwise direction of the strip (all along the length of the strip) via the stitching operation. Applicant's argument is not persuasive in this regard.

The applicant addressed Martin and stated that the processing in Martin were different from that claimed. Again, applicant is advised that the teachings of Martin are nonetheless relevant to the question of obviousness. The question to be answered is what kind of materials would one skilled in the art have chosen for the stent component in the operation of Cox et al. One would have understood that the conventional stent components included those described by Martin. To state that Martin is not relevant because Martin chose a different manufacturing technique is not the question which need be answered. The question to answer is whether one skilled in the art would have looked to Martin for the specific stent materials defined therein and used the same in Cox et al. As Cox et al is not specific to the materials, one skilled in the art of stent graft assembly would have been motivated to look to useful materials for the stent component and such would have included use of the materials of Martin in the processing of Cox et al.

Art Unit: 1733

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

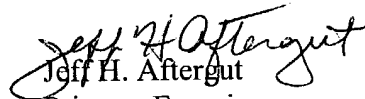
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff H. Aftergut whose telephone number is 571-272-1212. The examiner can normally be reached on Monday-Friday 7:15-345 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeff H. Aftergut
Primary Examiner
Art Unit 1733

JHA
April 27, 2004